

JUN - 2 2004

Making Process document.

EQUIVALENT (PREDICATE) DEVICE #1: X-Caliber Model 1000, X-Caliber CM Model 2000

510(k) Number K900681

Manufactured By: TAKARA BELMONT USA, Inc.
Somerset, New Jersey

EQUIVALENT (PREDICATE) DEVICE #2: PLANMECA 2002 CC Proline Panoramic X-ray

510(k) Number K970812

Manufactured By: PLANMECA OY
Asentajankatu 6
Helsinki, FI 00880

A. Do the X-Ray Imaging Device have the same indications statements?

Yes. ANA-BEL and ANA-BEL CM, Takara X-Caliber and X-Caliber CM, and PLANMECA 2002 CC Proline Panoramic X-ray are intended for the following use:

- Generation of radiographic images of the dento-maxillofacial region for dental examination and diagnosis of diseases of the teeth, jaw, and oral structures.

- B. Do the X-Ray Imaging Device have the same technological characteristics, e.g., design, materials, etc.?**

Yes. ANA-BEL and ANA-BEL CM, Takara X-Caliber and X-Caliber CM, and PLANMECA 2002 CC Proline Panoramic X-ray all employ X-ray tube with maximum rated peak tube potential of 90 kV. Please refer to the comparison table for specifications.

- C. Could the new characteristics affect safety and effectiveness?**

No.

- D. Do the new characteristics raise new types of safety or effectiveness questions?**

No.

- E. Do acceptable scientific methods exist for assessing effects of the new characteristics?**

Yes.

- F. Are performance data available to assess the effects of new characteristics?**

Yes.

- G. Do performance data demonstrate equivalence?**

Yes.

CONCLUSION:

The ANA-BEL and ANA-BEL CM, Takara X-Caliber and X-Caliber CM, and PLANMECA 2002 CC Proline Panoramic X-ray are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2004

Takara Belmont USA
% Mr. Jean-Claude Amar
Official Correspondent
Schiff & Company
1129 Bloomfield Avenue
WEST CALDWELL NJ 07006

Re: K040748
Trade/Device Name: ANA-BEL and
ANA-BEL CM
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: May 13, 2004
Received: May 14, 2004

Dear Mr. Amar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

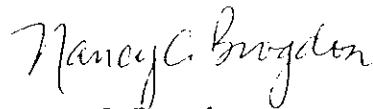
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Not assigned yet
Device Name: ANA-BEL and ANA-BEL CM

Indications for Use:

The ANA-BEL and ANA-BEL CM dental panoramic and cephalometric X-ray system is indicated for use as a generator of radiographic images of the dento-maxillofacial region and is intended for dental examination and diagnosis of diseases of the teeth, jaw, and oral structures.

Prescription Use ~~X~~

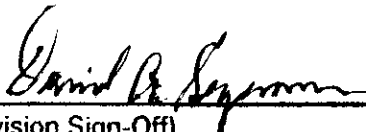
(Per 21 CFR 801 Subpart D)

Over-The-Counter Use _____

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K040748

SUBMITTED BY SCHIFF & COMPANY, WEST CALDWELL, NJ